
Technical Consultation Accelerating Essential Health Commodity Security

Through South-to-South Collaboration

The Concept Foundation (I)

- ◆ Who?
- ◆ When?
- ◆ Where?
- ◆ What?
- ◆ How?
- ◆ WHO, UNFPA, World Bank, IPPF
- ◆ Since 1989
- ◆ > 20 developing countries
- ◆ Reproductive Health
- ◆ Very small organization, works on outsourcing principle to provide quality services

The Concept Foundation (II)

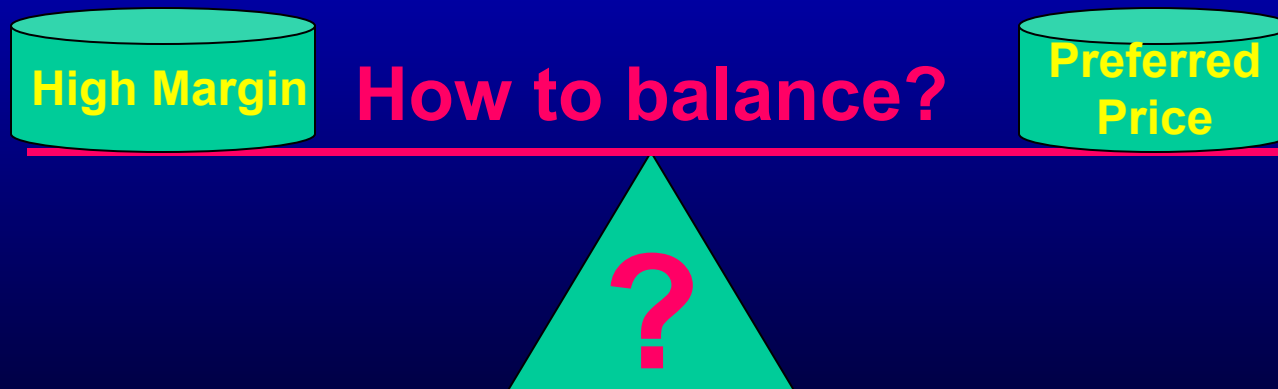
- ◆ **Products & Projects (6/2001)**

- ◆ **Cyclofem® - monthly injectable contraceptive**
- ◆ **HIV – Dipstick for rapid testing**
- ◆ **Postinor-2 as ECP**
- ◆ **Mifepristone (RU 486) development in China**

Business Model (I)

◆ **Private-sector enterprises need to look for financial success**

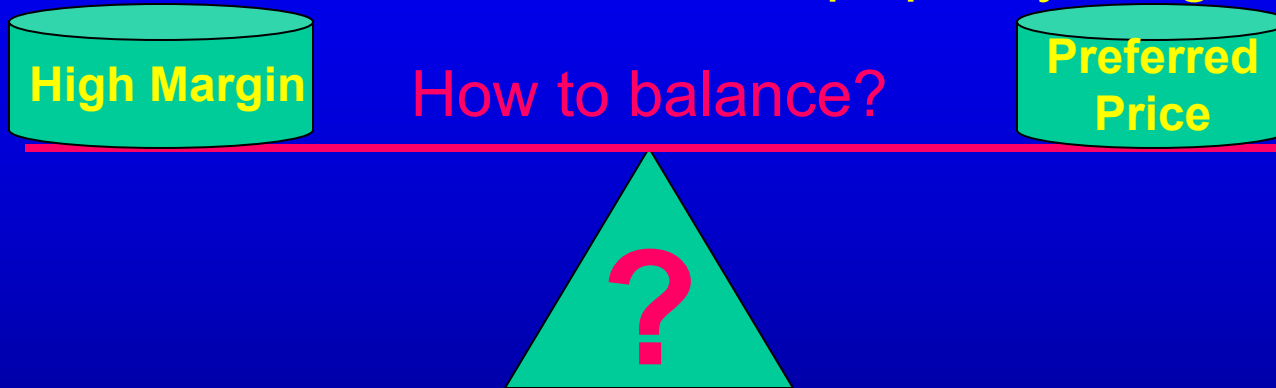
◆ **Public sector health-care needs access to low-cost / top-quality drugs**



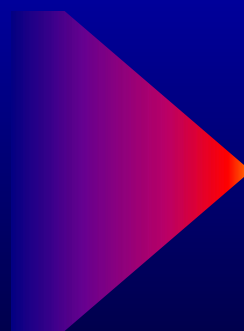
Business Model (II)

- ◆ Private enterprises need to look for financial success

- ◆ Public sector health-care needs access to low-cost / top-quality drugs



**Financial support
from public
sector**



**Cost benefit
back to public
sector**

Types of Financial Support (I)

- ◆ **Technology transfer**
- ◆ **Training & education: GMP, ISO, QC**
- ◆ **Clinical research by public-sector organizations**
- ◆ **Clinical trial data = Intellectual property**
- ◆ **Registration dossier**
- ◆ **Introductory / acceptance trials**
- ◆ **Quality assurance schemes**

Types of Financial Support (II)

- ◆ **Support tools need to result in an attractive VALUE PROPOSITION for the private-sector company:**
 - ➔ **Save time to market = higher market share expectations**
 - ➔ **Save resources = more parallel activities possible**
 - ➔ **Save investments = better cash-flow utilization**

Additional Benefits

- ◆ **Through clinical development, introductory trials & registration dossier:**
 - ⇒ **control over drug efficacy**

- ◆ **Through technology transfer & QA / QC schemes:**
 - ⇒ **Control over quality**

Successful Public-Private-Partnership Model

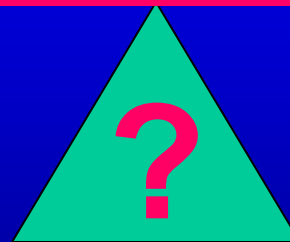
- ◆ Private enterprises need to look for financial success

- ◆ Public sector health-care needs access to low-cost / top-quality drugs

High Margin

How to balance?

Preferred Price



Financial support from public sector for:

- Clinical research
- Technology transfer
- Quality assurance
- Registration filing, etc.

Cost benefit to public sector:

- Preferred public sector pricing
- Low ROI target from industry, steady volumes

Business Model of TCF

- ◆ **Licensor to pharmaceutical companies**
- ◆ **Transfer intellectual property and technology to private-sector licensees**
- ◆ **Pre-finance their market entry**
- ◆ **Enable top-quality production for successful private-sector competition and sales**
 - ⇒ **Royalty source**
- ◆ **Mandate low-cost supply to public-sector health care services**
- ◆ **Utilize private-sector royalties to roll out product into more developing countries**

General Issues

- ◆ **Health commodities supply at public-sector prices alone isn't a sustainable business model for the private sector**
- ◆ **Need for attractive VALUE propositions from public sector**
 - ⇒ **Steady volumes through public channels**
 - ⇒ **Low-risk business, low marketing cost, small organizations, utilize existing infrastructures, etc. = low cost = low ROI**
- ◆ **REWARD: low-cost / top-quality**
- ◆ **Example: existing licensees**

Issue: Product Price

◆ Private sector:

- ➔ Retrograde calculation in view of affluence and affordability; costs of manufacturing are negligible, organizational costs dominate

◆ Public sector:

- ➔ Cost-plus model; costs of manufacturing are important as well as infrastructure cost, organizational costs need to be kept at minimum levels

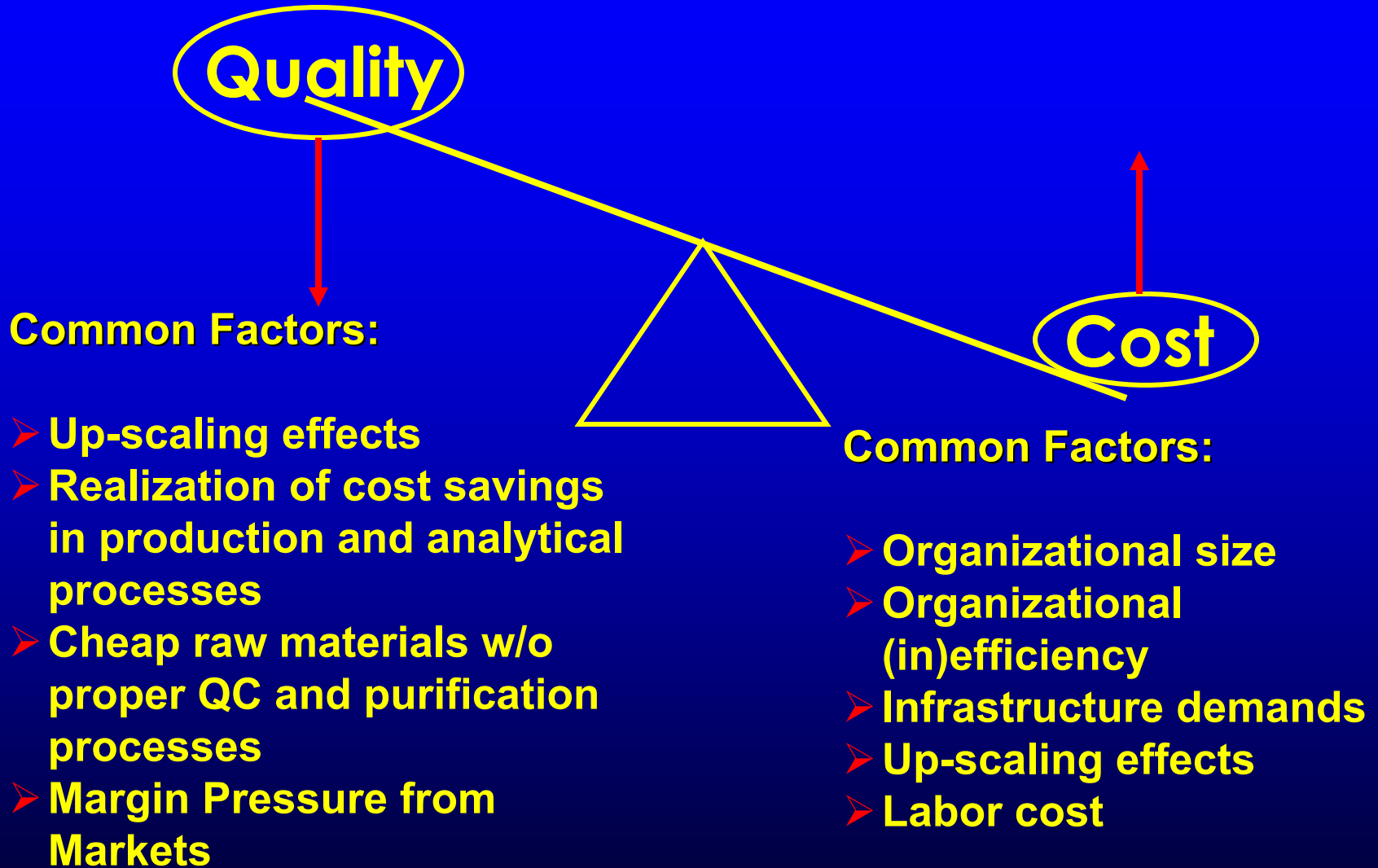
Issue: Product Price

Product cost structure for local generic manufacturer:



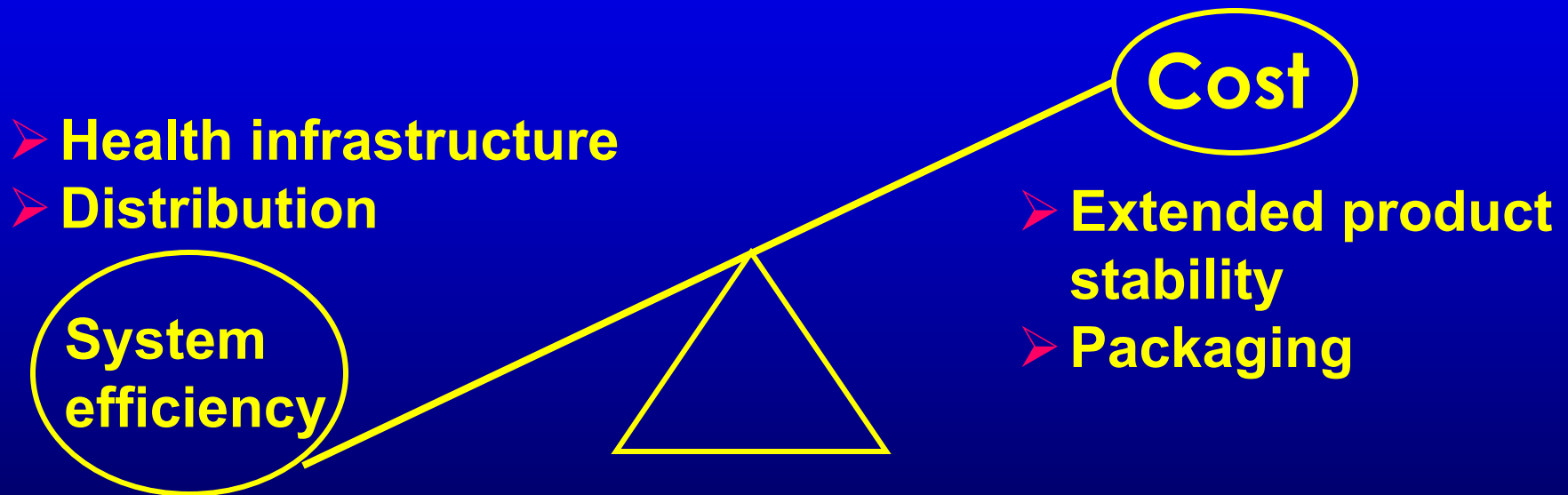
Σ : 30 - 40% cost reduction for public sector possible

Issue: Cost – Quality Balance



Issue: Infrastructure Demands

influences
Health infrastructure → Distribution efficiency →
Product stability demands → Packaging costs



Example: extended shelf-life requirements increase product cost significantly.

Issue: Quality

- ◆ **The Concept Foundation mandates licensees to have all certifications in place for top-quality delivery in private market competition**
 - ⇒ **GMP: standards for quality manufacturing environment with direct influence on product quality:**
 - Adequate pre-, peri-, post- manufacturing steps
 - Cleanliness, carry over etc.
 - Material conditions, storage etc.
- ◆ **Product quality is built into the product as result of product specifications, quality techniques used, technologies employed**

Issue: Quality

- ◆ **Quality assurance aimed at:**
 - ➔ **Qualifying manufacturing capabilities**
 - ➔ **Supervising compliance with quality standards for production**
 - ➔ **Supervising stable delivery of expected product properties**
- ◆ **Discontinuous scheme compared to:**
- ◆ **Industrial QC procedures at POP**
 - ➔ **Continuous monitoring if all production factors cooperate as designed**
 - **Hard factors: materials, machinery**
 - **Soft factors: environment, human resources**

Issue: QA / QC

- ◆ **Industrial experience:**
 - ⇒ **Continuous confirmation of product quality at POP is most efficient to guarantee constant quality**
 - ⇒ **Quality level is up to manufacturing spec's: subject to QA!**
- ◆ **Without industrial QC procedures in place QA schemes are no guarantee for quality of production**
- ◆ **Tendency of SME's to save QC cost!**

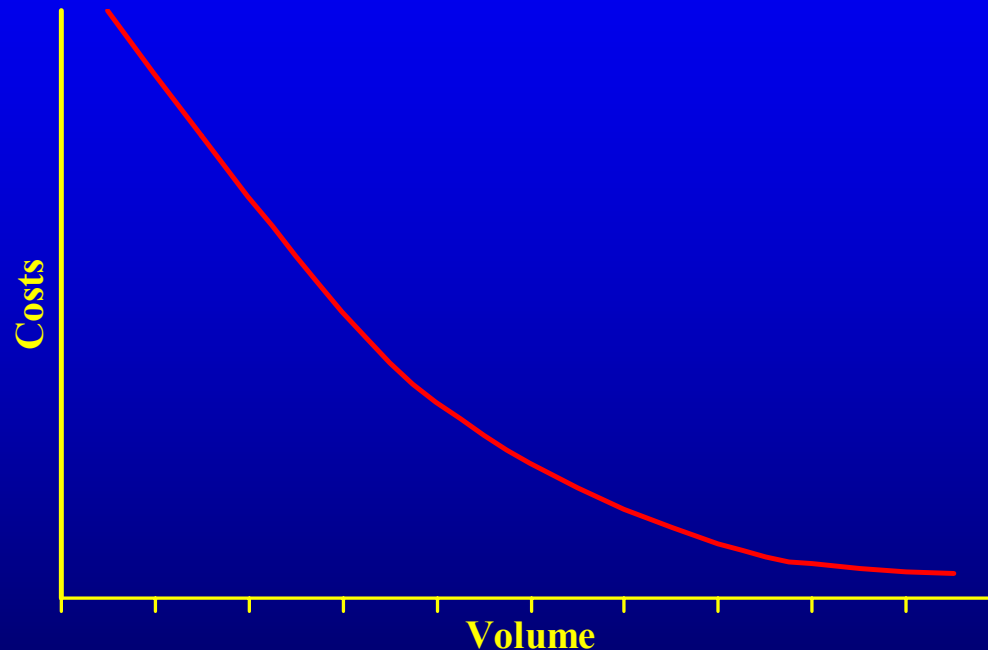
Issue: Quality

- ◆ **Clarification: ISO 900x**
 - ⇒ **Process-oriented certification**
 - ⇒ **NOT: product quality certification**
 - ⇒ **Knowledge how to perform processes by the workforce, and the uniform ability to reproduce these particular process steps across the workforce without individual variability**
- ◆ **“Service provider qualification”**
- ◆ **Not a quality guarantee; similar to IT situation: TI - TO**

Issue: Merit of Scale (I)

◆ Classical assumption:

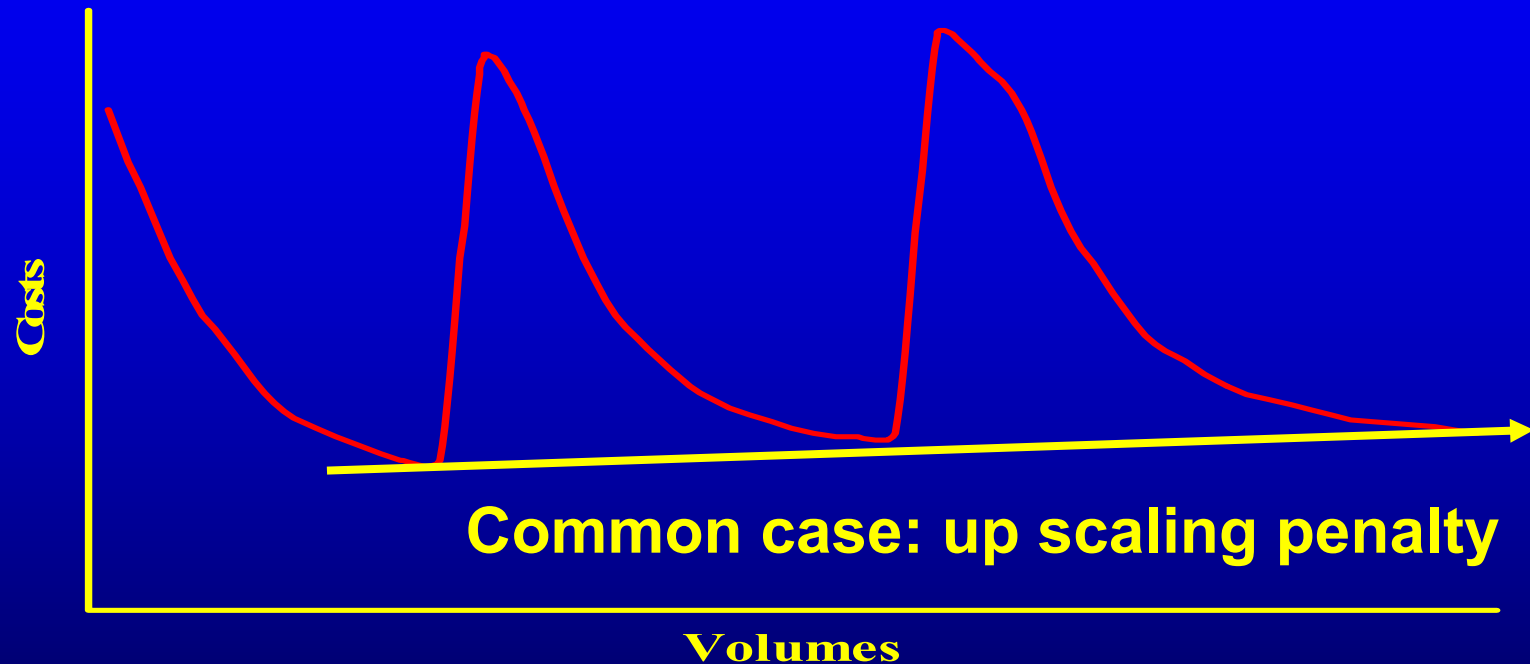
➡ higher volumes – lower cost



➡ Valid only within framework of capacity utilization of existing equipment

Issue: Merit of Scale (II)

- ◆ Volume demands beyond existing capacities result in a loss of cost position from upscaling:



- ◆ Cost position benefits from know-how and quality approach more than from volume effect

Collaboration Across Sectors

